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VIA ECF

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April 12, 2021

Honorable Alison J. Nathan  
United States District Judge  
United States District Court for the Southern District of New York  
40 Foley Square  
New York, NY 10007

Re: ***Regeneron Pharmaceuticals, Inc. v. Novartis Pharma AG et al.***, No. 1:20-cv-05502

Dear Judge Nathan:

I write on behalf of Plaintiff Regeneron Pharmaceuticals, Inc. (“Regeneron”) to respond to the April 7, 2021 letter submitted by the Novartis Defendants<sup>1</sup> regarding the withdrawal of their proceeding before the U.S. International Trade Commission (“ITC Action”), *Certain Prefilled Syringes for Intravitreal Injection and Components Thereof*, USITC No. 337-TA-1207 (I.T.C. June 19, 2020). *See* ECF No. 109.

As a threshold matter, Novartis’s letter is “damage control” in a transparent attempt to spin bad news. The ITC’s Office of Unfair Import Investigations (“ITC Staff”)—an ***independent, neutral*** party to the ITC Action—agreed that there was “clear and convincing evidence” that U.S. Patent No. 9,220,631 (“’631 Patent”) is ***invalid*** under 35 U.S.C. § 102(f) because Novartis failed to name Vetter employees as co-inventors and under 35 U.S.C. § 103 because prior art that was never submitted to and considered by the U.S. Patent & Trademark Office (“PTO”) renders the claimed invention obvious. *See Ex. A* attached hereto (“ITC Staff Brief”), at 31–92, 98–113. Twelve days after receiving the ITC Staff Brief, and less than two weeks before commencement of the scheduled ITC trial, Novartis moved to terminate the ITC Action. Novartis’s contention that it has abandoned the ITC Action because of public interest concerns and to “conserve substantial resources of the parties and of the ITC” is not credible. ECF No. 109. Novartis has been aware of those public interest concerns since at least July 6, 2020, when Regeneron and others filed public interest statements in response to Novartis’s ITC complaint. Nonetheless, Novartis proceeded with the ITC Action up to the precipice of trial. Put simply, Novartis dropped the ITC Action because it knew it was likely going to lose on the issue of invalidity.

Novartis’s abandonment of its ITC Action following the filing of the ITC Staff Brief further confirms the plausibility of Regeneron’s antitrust action against Defendants. First, the ITC Staff found clear and convincing evidence that Novartis’s ’631 Patent is invalid based on the very evidence that forms the basis of the inequitable conduct underlying Regeneron’s Sherman Act Section 2 *Walker Process* fraud claims

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<sup>1</sup> Novartis Pharma AG, Novartis Technology LLC, and Novartis Pharmaceuticals Corporation are referred to collectively as “Novartis Defendants.” Defendant Vetter Pharma International GmbH is referred to as “Vetter.”

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for: (1) Novartis’s omission of the Vetter inventors; and (2) Novartis’s omission of material prior art rendering the claimed invention obvious. *See* ECF No. 88 (“Am. Compl.”). As Regeneron informed this Court, Novartis brought the ITC Action and *omitted Vetter* from its required ITC disclosure of ’631 Patent licensees. *See* ECF No. 45 at 6, n.4. Months later, the ITC Staff concluded “there will be clear and convincing evidence that *the ’631 patent is invalid for improper inventorship*” because Novartis hid the Vetter inventors from the PTO. *Ex. A*, ITC Staff Br. at 98. In particular, the ITC Staff found that “one or more employees at Vetter should have been named as inventors of the ’631 patent based on their significant contribution[.]” *Id.* at 102. Notably, the ITC Staff identified the *same Vetter inventors* that Regeneron identified, while also rejecting Novartis’s argument—which Novartis made in the ITC Action and mistakenly advances in its Rule 12 motion to dismiss (ECF No. 92)—that the missing inventors must be identified specifically. *Ex. A*, ITC Staff Br. at 110.

Regeneron’s First Amended Complaint expressly pleads that the ’631 Patent is unenforceable because specific Novartis employees were aware of the Vetter inventors and purposely withheld their names from the PTO. *See* Am. Compl. ¶¶ 138–149. Regeneron also pleads that Novartis and Vetter entered into a collusive agreement to “settle” their dispute regarding the true Vetter inventors of the ’631 Patent and that Vetter obtained a substantial economic interest in return. *Id.* ¶¶ 149, 155–165, 178–180, 186–188. This conduct is part-and-parcel of Regeneron’s *Walker Process* claim against Novartis (Count IV), *id.* ¶¶ 277–283, overall attempted monopolization claim against Novartis (Count II), *id.* ¶¶ 239–241, unreasonable restraint of trade claim against Novartis and Vetter (Count III), *id.* ¶¶ 256–265, and tortious interference claim against Novartis (Count V), *id.* ¶¶ 286–292. And the very evidence underlying the ITC Staff’s findings in the ITC is now in the SDNY case. *See* ECF No. 102. The fact that a neutral third party found the evidence shows Vetter employees should have been named by Novartis as inventors of the ’631 Patent confirms, *at a minimum*, the sufficiency and plausibility of these allegations in Regeneron’s pleading.

Tellingly, Regeneron asked Novartis multiple times to withdraw the specious arguments advanced in its motion to dismiss that Novartis is supposedly unaware of the true Vetter inventors of the ’631 Patent. *See* ECF No. 107, at Sections IV.A.1, IV.A.3. As the evidence in the ITC Action makes clear (evidence that Novartis refused to produce in the SDNY until after Regeneron filed its First Amended Complaint in January 2021), Novartis undoubtedly knows the identity of the two Vetter inventors and that their omission was material to patentability. Novartis refused. *See Ex. B* attached hereto.<sup>2</sup>

Second, the ITC Staff agreed that there was clear and convincing evidence that Novartis’s ’631 Patent is obvious in light of patent application WO 2011/006877 (“WO ’877”), which was invented by Dr. Juergen Sigg at Novartis and published on January 22, 2011. *See Ex. A*, ITC Staff Br. at 45, 60. As part of Regeneron’s other *Walker Process* claim (Count I) and its attempted monopolization claim (Count II),

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<sup>2</sup> After Regeneron asked Novartis to provide Your Honor with a copy of the ITC Staff Brief, Novartis also refused, labeling it “extraneous materials.” *See Ex. B*. Novartis has apparently reversed its position to get ahead of this negative development. Novartis’s letter to this Court now discusses the ITC Staff Brief at length and agreed “to submit a copy to the Court immediately,” conceding that the ITC Staff Brief is relevant to this Court’s consideration. ECF No. 109. Regeneron also requested that Novartis consent to provide Your Honor with an unredacted, confidential version of the ITC Staff Brief. Novartis has yet to consent. *See Ex. B*.

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Regeneron also pleads that Novartis employees, including Dr. Sigg (a named inventor of the '631 Patent), were aware of this material prior art (WO '877) and deliberately failed to disclose it to the PTO despite an ongoing duty of candor. *See* Am. Compl. ¶¶ 112, 125–129, 132–137, 219–222, 238. Here, too, the ITC Staff's conclusion that WO '877 renders the '631 Patent obvious confirms the plausibility of these allegations in Regeneron's First Amended Complaint, indicating that the PTO would not have issued the '631 Patent had it known about WO '877.

Although an ITC proceeding does not have preclusive effect, district courts consider the views of the independent ITC Staff and ITC developments. *See, e.g., Bio-Technology Gen. Corp. v. Genentech Inc.*, 886 F. Supp. 377, 381 (S.D.N.Y. 1995) (considering “findings of the ALJ in the ITC proceeding” on a motion to dismiss sham litigation claim); *SanDisk Corp. v. ST Microelectronics, Inc.*, No. 04-4379, 2008 WL 4615605, at \*10 (N.D. Cal. Oct. 17, 2008) (referencing ITC's findings in holding that SanDisk's ITC litigation barred ST's sham litigation counterclaim); *In re VISX, Inc. Secs Litig.*, No. 00-0649, 2001 WL 210481, at \*7 (N.D. Cal. Feb. 27, 2001) (taking judicial notice of ITC staff brief and ITC ALJ's findings on co-inventorship, which “support[] an inference that [plaintiff's] claim has some validity”); *Apple, Inc. v. Motorola Mobility, Inc.*, No. 11-178, 2012 WL 5416941, at \*10 (W.D. Wisc. Oct. 29, 2012) (stating that “findings by the ITC can be considered by district courts for their persuasive value” and taking judicial notice of ITC staff brief and ITC ALJ's findings on invalidity). While Novartis's withdrawal prevented the ALJ from ruling on the invalidity of the '631 Patent in the ITC Action, the same reasoning applies here to the ITC Staff Brief, which is persuasive authority showing that key aspects of Regeneron's antitrust claims are sufficiently and plausibly pled.

Regeneron's antitrust claims in this case are even more critical now in holding Novartis accountable.<sup>3</sup> Despite the ITC Staff's findings of clear and convincing evidence of invalidity on several separate grounds, and Novartis's resultant motion to terminate the ITC Action, Novartis vows to double-down on its anticompetitive conduct and “vigorously prosecute its patent infringement claim in the U.S. District Court for the Northern District of New York.” ECF 109 at 3. To that end, Novartis has filed a status report in the NDNY case asking for a lifting of the stay in that action. Regeneron has until April 16, 2021, to respond to Novartis's status report in the NDNY, and Regeneron will provide a copy of its submission to this Court at that time. As for Novartis's request that the Court schedule any oral argument on Novartis's Motion to Dismiss, Transfer, or Stay, Regeneron defers to the Court on the scheduling of oral argument.

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Regeneron continues to move its antitrust case forward in this forum and is happy to address any questions the Court may have or to provide any additional information.

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<sup>3</sup> Novartis misrepresents to this Court that “the N.D.N.Y. Action was filed by Novartis but stayed by Regeneron, *all prior to the filing by Regeneron of this action.*” ECF No. 109, at 3 n.4 (emphasis added). That is false. As explained in Regeneron's opposition (ECF No. 45, at 4-5, 7-8), Regeneron filed this antitrust action in the SDNY on July 17, 2020. On July 28, 2020—11 days later—Regeneron moved to stay the NDNY case as a matter of statutory right. Novartis ***did not oppose this request***, and the case was stayed on July 30, 2020. Novartis was thus well-aware of Regeneron's SDNY antitrust action when it consented to the stay in the NDNY case. Further, Novartis never even mentioned transferring Regeneron's antitrust action when the parties conferred on the NDNY stay. Novartis instead reversed course a month later when it filed its motion to transfer in the SDNY.

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Respectfully submitted,

*/s/ Eric S. Hochstadt*

Eric S. Hochstadt

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Pharmaceuticals, Inc.*